



ATTORNEYS AT LAW



Robert Greene Sterne  
Jorge A. Goldstein  
David K.S. Comwell  
Robert W. Esmond  
Tracy-Gene G. Durkin  
Michele A. Cimbala  
Michael B. Ray  
Robert E. Sokohl  
Eric K. Steffe  
Michael Q. Lee  
John M. Covert  
Robert C. Millonig  
Donald J. Featherstone  
Timothy J. Shea, Jr  
Michael V. Messinger  
Judith U. Kim  
Jeffrey T. Helvey  
Eldora L. Ellison  
Donald R. Banowitz

Peter A. Jackman  
Brian J. Del Buono  
Mark Fox Evans  
Vincent L. Capuano  
Elizabeth J. Haanes  
Michael D. Specht  
Kevin W. McCabe  
Glenn J. Perry  
Edward W. Yee  
Grant E. Reed  
Virgil Lee Beaston  
Theodore A. Wood  
Joseph S. Ostroff  
Jason D. Eisenberg  
Tracy L. Muller  
Jon E. Wright  
LuAnne M. DeSantis  
Ann E. Summerfield  
Helene C. Carlson

Cynthia M. Bouchez  
Timothy A. Doyle  
Gaby L. Longsworth  
Lori A. Gordon  
Laura A. Vogel  
Bryan S. Wade  
Bashir M.S. Ali  
Shannon A. Carroll  
Anbar F. Khal  
Michelle K. Holoubek  
Marsha A. Rose  
Scott A. Schaller  
Lei Zhou  
Young Tang  
Christopher J. Walsh  
W. Blake Coblenz\*  
James J. Pohl  
John T. Haran  
Mark W. Rygiel

Michael R. Malek\*  
Carla Ji-Eun Kim  
Doyle A. Siever\*  
Ulrike Winkler  
Bryan L. Skelton\*  
Paul A. Cahvo  
Robert A. Schwartzman  
C. Matthew Rozier  
Alexandra K. Pechhold  
Registered Patent Agents\*  
Karen R. Markowicz  
Matthew J. Dowd  
Katrina Yujian Pei Quach  
Julie A. Heider  
Mita Mukherjee

Scott M. Woodhouse  
Peter A. Socarras  
Jeffrey K. Mills  
Danielle L. Letting  
Lori Brandes  
Steven C. Oppenheimer  
Aaron S. Lukas  
Gaurav Asthana

Of Counsel  
Edward J. Kessler  
Kenneth C. Bass III  
Marvin C. Guthrie  
Christopher P. Wrist  
\*Admitted only in Maryland  
+Admitted only in Virginia  
•Practice Limited to Federal Agencies

June 14, 2007

WRITER'S DIRECT NUMBER:  
(202) 772-8591

INTERNET ADDRESS:  
JMILLS@SKGF.COM

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Art Unit 1644

Attn: Mail Stop Amendment

Re: U.S. Utility Patent Application  
Application No. 09/914,046; Filed: October 1, 2001  
For: **Antibody Fragment-Targeted Immunoliposomes for Systemic Gene Delivery**  
Inventors: XU *et al.*  
Our Ref: 2474.0010001/BJD/JKM

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover the Information Disclosure Statement fee;
2. Second Supplemental Information Disclosure Statement;
3. List of cited references on Form PTO/SB/08A (1 sheet);
4. List of cited references on Form PTO/SB/08B (7 sheets);
5. Copies of references **NPL1-NPL69** listed on Form PTO/SB/08B (69 documents); and
6. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

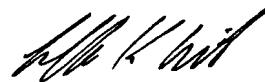
In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
June 14, 2007  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Jeffrey K. Mills  
Agent for Applicants  
Registration No. 56,413

BJD/JKM:bac  
Enclosures

687213\_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

XU *et al.*

Appl. No.: 09/914,046

Filed: October 1, 2001

For: **Antibody Fragment-Targeted  
Immunoliposomes for Systemic  
Gene Delivery**

Confirmation No.: 8537

Art Unit: 1644

Examiner: Dibrino, M.

Atty. Docket: 2474.0010001/BJD/JKM

**Second Supplemental Information Disclosure Statement  
Under 37 C.F.R. § 1.97(c)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **NPL1** to **NPL69** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, **US1** and **US2**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

06/15/2007 MAHMED1 00000180 09914046

01 FC:1806

180.00 0P

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

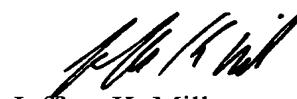
This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 payment amount in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



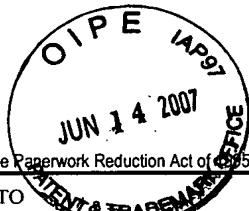
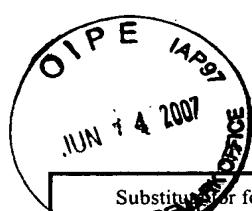
Jeffrey K. Mills  
Agent for Applicants  
Registration No. 56,413

Date: June 14, 2007

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

682325\_1

Atty. Dkt. No. 2474.0010001/BJD/JKM



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Approved for use through 03/31/2007. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Do not send a collection of information unless it contains a valid OMB control number.

Substitution for form 1449/PTO  
U.S. PATENT & TRADEMARK OFFICE

**SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

<i>Complete if Known</i>	
Application Number	09/914,046
Filing Date	October 1, 2001
First Named Inventor	XU, Liang
Art Unit	1644
Examiner Name	Dibrino, M.
Attorney Docket Number	2474.0010001/BJD/JKM

---

**U.S. PATENT DOCUMENTS**

---

## FOREIGN PATENT DOCUMENTS

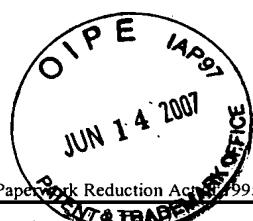
678604 1

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Equivalent of Form PTO/SB/08B (09-06)  
 Approved for use through 03/31/2007. OMB 0651-0031  
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Application Number	09/914,046
Sheet <b>1</b> of <b>7</b>				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
				Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	ALLEN, T.M., <i>et al.</i> , "A new strategy for attachment of antibodies to sterically stabilized liposomes resulting in efficient targeting to cancer cells," <i>Biochim. Biophys. Acta</i> 1237:99-108, Elsevier Science Inc. (1995)	
	NPL2	ALLEN, T.M., <i>et al.</i> , "Antibody-Targeted Stealth <sup>®</sup> Liposomes" in <i>Stealth Liposomes</i> , Lasic, D.D. and Martin, F.J., eds., CRC Press Inc., Boca Raton, FL, pp. 233-244 (1995)	
	NPL3	AOKI, K., <i>et al.</i> , "Liposome-mediated <i>in Vivo</i> Gene Transfer of Antisense K-ras Construct Inhibits Pancreatic Tumor Dissemination in the Murine Peritoneal Cavity," <i>Cancer Res.</i> 55:3810-3816, American Association for Cancer Research (1995)	
	NPL4	BAJORIA, R., and CONTRACTOR, S.F., "Effect of Surface Charge of Small Unilamellar Liposomes on Uptake and Transfer of Carboxyfluorescein across the Perfused Human Term Placenta," <i>Pediatr. Res.</i> 42:520-527, International Pediatrics Research Foundation, Inc. (1997)	
	NPL5	BAJORIA, R., <i>et al.</i> , "Endocytotic uptake of small unilamellar liposomes by human trophoblast cells in culture," <i>Hum. Reprod.</i> 12:1343-1348, European Society for Human Reproduction and Embryology (1997)	
	NPL6	BRISTOW, R.G., <i>et al.</i> , "The p53 gene as a modifier of intrinsic radiosensitivity: implications for radiotherapy," <i>Radiother. Oncol.</i> 40:197-223, Elsevier Scientific Publishers (1996)	
	NPL7	CHEN, L., <i>et al.</i> , "Synergistic activation of p53 by inhibition of MDM2 expression and DNA damage," <i>Proc. Natl. Acad. Sci. USA</i> 95:195-200, National Academy of Sciences (1998)	
	NPL8	CHENG, P.-W., "Receptor Ligand-Facilitated Gene Transfer: Enhancement of Liposome-Mediated Gene Transfer and Expression by Transferrin," <i>Hum. Gene Ther.</i> 7:275-282, Mary Ann Liebert, Inc. (1996)	
	NPL9	CHIARUGI, V., <i>et al.</i> , "Cox-2, iNOS and p53 as play-makers of tumor angiogenesis (Review)," <i>Int. J. Mol. Med.</i> 2:715-719, D.A. Spandidos (1998)	
	NPL10	CLARK, P.R., and HERSH, E.M., "Cationic lipid-mediated gene transfer: Current concepts," <i>Curr. Opin. Mol. Ther.</i> 1:158-176, Current Drugs Ltd. (April 1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	09/914,046
				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
Sheet	2	of	7	Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published		T <sup>2</sup>
	NPL11	CRISTIANO, R.J., and CURIEL, D.T., "Strategies to accomplish gene delivery via the receptor-mediated endocytosis pathway," <i>Cancer Gene Ther.</i> 3:49-57, Appleton & Lange (1996)		
	NPL12	DRUMMOND, D.C., <i>et al.</i> , "Optimizing Liposomes for Delivery of Chemotherapeutic Agents to Solid Tumors," <i>Pharmacol. Rev.</i> 51:691-743, The American Society for Pharmacology and Experimental Therapeutics (December 1999)		
	NPL13	DUBÉ, D., <i>et al.</i> , "Preparation and Tumor Cell Uptake of Poly( <i>N</i> -isopropylacrylamide) Folate Conjugates," <i>Bioconjugate Chem.</i> 13:685-692, American Chemical Society (May-June 2002)		
	NPL14	ELLIOTT, R.L., <i>et al.</i> , "Breast Carcinoma and the Role of Iron Metabolism: A Cytochemical, Tissue Culture, and Ultrastructural Study," <i>Ann. N.Y. Acad. Sci.</i> 698:159-166, New York Academy of Sciences (1993)		
	NPL15	FELGNER, P.L., <i>et al.</i> , "Improved Cationic Lipid Formulations for <i>In Vivo</i> Gene Therapy," <i>Ann. N.Y. Acad. Sci.</i> 772:126-139, New York Academy of Sciences (1995)		
	NPL16	FORSSEN, E., and WILLIS, M., "Ligand-targeted liposomes," <i>Adv. Drug Deliv. Rev.</i> 29:249-271, Elsevier Science B.V. (1998)		
	NPL17	FUJIWARA, T., <i>et al.</i> , "A Retroviral Wild-Type <i>p53</i> Expression Vector Penetrates Human Lung Cancer Spheroids and Inhibits Growth by Inducing Apoptosis," <i>Cancer Res.</i> 53:4129-4133, American Association for Cancer Research (1993)		
	NPL18	FUJIWARA, T., <i>et al.</i> , "Induction of Chemosensitivity in Human Lung Cancer Cells <i>in vivo</i> by Adenovirus-mediated Transfer of the Wild-Type <i>p53</i> Gene," <i>Cancer Res.</i> 54:2287-2291, American Association for Cancer Research (1994)		
	NPL19	HAMADA, K., <i>et al.</i> , "Adenovirus-mediated Transfer of a Wild-Type <i>p53</i> Gene and Induction of Apoptosis in Cervical Cancer," <i>Cancer Res.</i> 56:3047-3054, American Association for Cancer Research (1996)		
	NPL20	HUWYLER, J., <i>et al.</i> , "Brain drug delivery of small molecules using immunoliposomes," <i>Proc. Natl. Acad. Sci. USA</i> 93:14164-14169, National Academy of Sciences (1996)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	09/914,046
				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
Sheet	3	of	7	Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL21	JOHNSON, P., <i>et al.</i> , "Expression of Wild-Type p53 Is Not Compatible with Continued Growth of p53-Negative Tumor Cells," <i>Mol. Cell Biol.</i> 11:1-11, American Society for Microbiology (1991)	
	NPL22	KERR, J.F.R., <i>et al.</i> , "Apoptosis: Its Significance in Cancer and Cancer Therapy," <i>Cancer</i> 73:2013-2026, Wiley (1994)	
	NPL23	KIRPOTIN, D., <i>et al.</i> , "Sterically Stabilized Anti-HER2 Immunoliposomes: Design and Targeting to Human Breast Cancer Cells <i>in Vitro</i> ," <i>Biochemistry</i> 36:66-75, American Chemical Society (1997)	
	NPL24	KONING, G.A., <i>et al.</i> , "Antiproliferative effect of immunoliposomes containing 5-fluorodeoxyuridine-dipalmitate on colon cancer cells," <i>Br. J. Cancer</i> 80:1718-1725, Cancer Research Campaign (August 1999)	
	NPL25	KONING, G.A., <i>et al.</i> , "Selective transfer of a lipophilic prodrug of 5-fluorodeoxyuridine from immunoliposomes to colon cancer cells," <i>Biochim. Biophys. Acta</i> 1420:153-167, Elsevier Science B.V. (August 1999)	
	NPL26	KONISHI, H., <i>et al.</i> , "Targeting Strategy for Gene Delivery to Carcinoembryonic Antigen-Producing Cancer Cells by Retrovirus Displaying a Single-Chain Variable Fragment Antibody," <i>Hum. Gene Ther.</i> 9:235-248, Mary Ann Liebert, Inc. (1998)	
	NPL27	LASIC, D.D., <i>et al.</i> , "Sterically stabilized liposomes in cancer therapy and gene delivery," <i>Curr. Opin. Mol. Ther.</i> 1:177-185, Current Drugs Ltd. (April 1999)	
	NPL28	LASIC, D.D., and PAPAHADJOPOULOS, D., "Liposomes Revisited," <i>Science</i> 267:1275-1276, American Association for the Advancement of Science (1995)	
	NPL29	LEE, R.J. and HUANG, L., "Folate-targeted, Anionic Liposome-entrapped Polylysine-condensed DNA for Tumor Cell-specific Gene Transfer," <i>J. Biol. Chem.</i> 271:8481-8487, American Society for Biochemistry and Molecular Biology, Inc. (1996)	
	NPL30	LEWIS, J.G., <i>et al.</i> , "A serum-resistant cytofectin for cellular delivery of antisense oligodeoxynucleotides and plasmid DNA," <i>Proc. Natl. Acad. Sci. USA</i> 93:3176-3181, National Academy of Sciences (1996)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	09/914,046
				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
Sheet	4	of	7	Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL31	LI, S., and HUANG, L., "Functional Pleomorphism of Liposomal Gene Delivery Vectors--Lipoplex and Lipopolplex," in <i>Liposomes--Rational Design</i> , Janoff, A.S., ed., Marcel Dekker, Inc., New York, NY, pp. 89-124 (1998)	
	NPL32	LIU, T.J., <i>et al.</i> , "Growth Suppression of Human Head and Neck Cancer Cells by the Introduction of a Wild-Type <i>p53</i> Gene via a Recombinant Adenovirus," <i>Cancer Res.</i> 54:3662-3667, American Association for Cancer Research (1994)	
	NPL33	LOWE, S.W., "Cancer therapy and <i>p53</i> ," <i>Curr. Opin. Oncol.</i> 7:547-553, Rapid Science Publishers (1995)	
	NPL34	MARTIN, F., <i>et al.</i> , "Retroviral Vector Targeting to Melanoma Cells by Single-Chain Antibody Incorporation in Envelope," <i>Human Gene Ther.</i> 9:737-746, Mary Ann Liebert, Inc. (1998)	
	NPL35	MASSING, U., "Cancer therapy with liposomal formulations of anticancer drugs," <i>Int. J. Clin. Pharmacol. Ther.</i> 35:87-90, Distriv-Verlag Dr. K. Feistle (1997)	
	NPL36	MATLASHEWSKI, G., "p53: Twenty years on, Meeting Review," <i>Oncogene Rev.</i> 18:7618-7620, Stockton Press (December 1999)	
	NPL37	MIYAMOTO, T., <i>et al.</i> , "Transferrin receptor in oral tumors," <i>Int. J. Oral Maxillofac. Surg.</i> 23:430-433, Munksgaard (1994)	
	NPL38	MIYASHITA, T., <i>et al.</i> , "Tumor suppressor <i>p53</i> is a regulator of <i>bcl-2</i> and <i>bax</i> gene expression in vitro and in vivo," <i>Oncogene</i> 9:1799-1805, Macmillan Press Ltd. (1994)	
	NPL39	NAG, A., <i>et al.</i> , "A Colorimetric Estimation of Polyethyleneglycol-Conjugated Phospholipid in Stealth Liposomes," <i>Anal. Biochem.</i> 250:35-43, Academic Press (1997)	
	NPL40	NAM, S.M., <i>et al.</i> , "Sterically Stabilized Anti- <i>G<sub>M3</sub></i> , anti- <i>Le<sup>x</sup></i> Immunoliposomes: Targeting to B16BL6, HRT-18 Cancer Cells," <i>Oncol. Res.</i> 11:9-16, Cognizant Communication Corporation (July 1999)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	09/914,046
				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
Sheet	5	of	7	Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published		T <sup>2</sup>
	NPL41	NG, K.-Y., <i>et al.</i> , "The effects of polyethyleneglycol (PEG)-derived lipid on the activity of target-sensitive immunoliposome," <i>Int. J. Pharma.</i> 193:157-166, Elsevier Science B.V. (January 2000)		
	NPL42	NICHOLSON, I.C., <i>et al.</i> , "Construction and Characterisation of a Functional CD19 Specific Single Chain Fv Fragment for Immunotherapy of B Lineage Leukaemia and Lymphoma," <i>Mol. Immunol.</i> 34:1157-1165, Elsevier Science Ltd. (1997)		
	NPL43	PAGNAN, G., <i>et al.</i> , "GD2-Mediated Melanoma Cell Targeting and Cytotoxicity of Liposome-Entrapped Fenretinide," <i>Int. J. Cancer</i> 81:268-274, Wiley-Liss, Inc. (April 1999)		
	NPL44	PARK, J.W., <i>et al.</i> , "Development of anti-p185 <sup>HER2</sup> immunoliposomes for cancer therapy," <i>Proc. Natl. Acad. Sci. USA</i> 92:1327-1331, National Academy of Sciences (1995)		
	NPL45	PARK, J.W., <i>et al.</i> , "Tumor targeting using anti-her2 immunoliposomes," <i>J. Control. Rel.</i> 74:95-113, Elsevier Science B.V. (July 2001)		
	NPL46	PIROLLO, K.F., <i>et al.</i> , "p53 mediated sensitization of squamous cell carcinoma of the head and neck to radiotherapy," <i>Oncogene</i> 14:1735-1746, Stockton Press (1997)		
	NPL47	PIROLLO, K.F., <i>et al.</i> , "Immunoliposomes: A Targeted Delivery Tool for Cancer Treatment," in <i>Vector Targeting for Therapeutic Gene Delivery</i> , Curiel, D.T., and Douglas, J.T., eds., Wiley-Liss, Inc., Hoboken, NJ, pp. 33-62 (August 2002)		
	NPL48	POON, R.Y.M, "Advances in Monoclonal Antibody Applications: Bispecific Antibodies" in <i>Biotechnology International: International Developments in the Biotechnology Industry</i> , Fox, F., and Connor, T.H., eds., Universal Medical Press, Inc., San Francisco, CA, pp. 113-128 (1997)		
	NPL49	RAIT, A.S., <i>et al.</i> , "Inhibitory effects of the combination of HER-2 antisense oligonucleotide and chemotherapeutic agents used for the treatment of human breast cancer," <i>Cancer Gene Ther.</i> 8:728-739, Nature Publishing Group (October 2001)		
	NPL50	ROH, H., <i>et al.</i> , "HER2/neu antisense targeting of human breast carcinoma," <i>Oncogene</i> 19:6138-6143, Macmillan Publishers Ltd. (December 2000)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	09/914,046
				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
Sheet	6	of	7	Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published			T <sup>2</sup>
	NPL51	RULEY, H.E., "p53 and Response to Chemotherapy and Radiotherapy," in <i>Important Adv. Oncol.</i> 1996, DeVita, V.T., <i>et al.</i> , eds., Lippincott-Raven Publishers, Philadelphia, PA, pp. 37-56 (1996)			
	NPL52	SCHIER, R., <i>et al.</i> , "In vitro and in vivo characterization of a human anti-c-erbB-2 single-chain Fv isolated from a filamentous phage antibody library," <i>Immunotechnology</i> 1:73-81, Elsevier Science B.V. (1995)			
	NPL53	SHAHINIAN, S., and SILVIUS, J.R., "A novel strategy affords high-yield coupling of antibody Fab' fragments to liposomes," <i>Biochim. Biophys. Acta</i> 1239:157-167, Elsevier Science B.V. (1995)			
	NPL54	SIDRANSKY, D., and HOLLSTEIN, M., "Clinical implications of the p53 gene," <i>Annu. Rev. Med.</i> 47:285-301, Annual Reviews, Inc. (1996)			
	NPL55	SRIVASTAVA, S., <i>et al.</i> , "Recombinant Adenovirus Vector Expressing Wild-type p53 is a Potent Inhibitor of Prostate Cancer Cell Proliferation," <i>Urology</i> 46:843-848, Excerpta Medica, Inc. (1995)			
	NPL56	SUZUKI, S., <i>et al.</i> , "Modulation of doxorubicin resistance in a doxorubicin-resistant human leukaemia cell by an immunoliposome targeting transferring receptor," <i>Br. J. Cancer</i> 76:83-89, Cancer Research Campaign (1997)			
	NPL57	The Journal of Gene Medicine Clinical Trials Database, "Gene Therapy Clinical Trials Worldwide," available online at <a href="http://www.wiley.co.uk/wileychi/genmed/clinical">http://www.wiley.co.uk/wileychi/genmed/clinical</a> , John Wiley and Sons, Ltd., 2 pages (accessed September 2001)			
	NPL58	THIERRY, A.R., <i>et al.</i> , "Systemic gene therapy: Biodistribution and long-term expression of a transgene in mice," <i>Proc. Natl. Acad. Sci. USA</i> 92:9742-9746, National Academy of Science (1995)			
	NPL59	THORSTENSEN, K. and ROMSLO, I., "The Transferrin Receptor: Its Diagnostic Value and its Potential as Therapeutic Target," <i>Scand. J. Clin. Lab. Invest.</i> 53 (Suppl. 215):113-120, Universitetsforlaget (1993)			
	NPL60	VERTUT-DOÏ, A., <i>et al.</i> , "Binding and uptake of liposomes containing a poly(ethylene glycol) derivative of cholesterol (stealth liposomes) by the macrophage cell line J774: influence of PEG content and its molecular weight," <i>Biochim. Biophys. Acta</i> 1278:19-28, Elsevier Science B.V. (1996)			

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	09/914,046
				Filing Date	October 1, 2001
				First Named Inventor	XU, Liang
				Art Unit	1644
				Examiner Name	Dibrino, M.
Sheet	7	of	7	Attorney Docket Number	2474.0010001/BJD/JKM

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL61	VOLPERT, O.V., <i>et al.</i> , "Sequential development of an angiogenic phenotype by human fibroblasts progressing to tumorigenicity," <i>Oncogene</i> 14:1495-1502, Stockton Press (1997)	
	NPL62	WEINBERG, E.D., "Roles of Iron in Neoplasia: Promotion, Prevention, and Therapy," <i>Biol. Trace Element Res.</i> 34:123-140, Humana Press, Inc. (1992)	
	NPL63	XU, L., <i>et al.</i> , "Systemic p53 gene therapy in combination with radiation results in human tumor regression," <i>Tumor Targeting</i> 4:92-104, Stockton Press (July 1999)	
	NPL64	XU, L., <i>et al.</i> , "Transferrin-Liposome-Mediated Systemic p53 Gene Therapy in Combination with Radiation Results in Regression of Human Head and Neck Cancer Xenografts," <i>Hum. Gene Ther.</i> 10:2941-2952, Mary Ann Liebert, Inc. (December 1999)	
	NPL65	XU, L., <i>et al.</i> , "Self-Assembly of a Virus-Mimicking Nanostructure System for Efficient Tumor-Targeted Gene Delivery," <i>Hum. Gene Ther.</i> 13:469-481, Mary Ann Liebert, Inc. (February 2002)	
	NPL66	XU, L., <i>et al.</i> , "Systemic Tumor-targeted Gene Delivery by Anti-Transferin Receptor scFv-Immunoliposomes," <i>Mol. Cancer Ther.</i> 1:337-346, American Association for Cancer Research (March 2002)	
	NPL67	YANG, C., <i>et al.</i> , "Adenovirus-mediated Wild-Type p53 Expression Induces Apoptosis and Suppresses Tumorigenesis of Prostatic Tumor Cells," <i>Cancer Res.</i> 55:4210-4213, American Association for Cancer Research (1995)	
	NPL68	YAZDI, P.T., <i>et al.</i> , "Influence of Cellular Trafficking on Protein Synthesis Inhibition of Immunotoxins Directed against the Transferrin Receptor," <i>Cancer Res.</i> 55:3763-3771, American Association for Cancer Research (1995)	
	NPL69	ZHANG, W.-W., <i>et al.</i> , "Advances in Cancer Gene Therapy," <i>Adv. Pharmacol.</i> 32:289-341, Academic Press, Inc. (1995)	

682128\_1

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.